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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,189

12/16/2005

Bjarne H. Dahl

2815-0335PUS1

3923

2292 7590 02/18/2009  
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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

02/18/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,189	<b>Applicant(s)</b> DAHL ET AL.	
	<b>Examiner</b> Susannah Chung	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 9-12 and 14-16 are pending in the instant application. Claims 1-8 and 13 are canceled.

#### ***Response to Non-Final Office Action***

Acknowledgment is made of applicant's response and amendment of the claims filed on 11/17/2008.

#### **112 Rejection**

Claims 11 and 12 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicants amendment to the claims and response have been considered, but are not found persuasive.

Applicants stated that the enablement rejection is overcome because of the amendment to the compound claims. The enablement rejection was not based on the scope of the compounds claimed, but it was on the scope of the diseases claimed. Applicants have claimed that the instantly claimed compounds can treat every disease linked to blockade of chloride channels. This results in an unlimited number of disorders all of which are not enabled. See the previous office action mailed on 7/15/08, especially pages 4-6, where the lack of enablement of the disorders is discussed. Therefore, the enablement rejection of claims 11 and 12 are made final.

#### **ODP Rejection**

Claims 1, 9, 10, 11 and 12 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-15 of U.S. Patent Num. 6,297,261 B1 ('261 Patent); Claims 1-13 of U.S. Patent Num. 6,696,475 B2 ('475 Patent);

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Claims 12-20 of U.S. Patent App. Num. 2006/0058395 A1 ('395 App); and Claims 21-39 of U.S. Patent App. Num. 2006/0160856 A1 ('856 App). Applicants have amended the claims so that the only compounds pending all have a 3'-trifluoromethyl-substituted biphenyl group.

Applicants arguments and amendments to the claims have been considered, but are not found persuasive. The 3'-trifluoromethyl-substituted biphenyl group is found in the genus and/or species claims cited. For example, see '261 Patent, claim 3, column 17, approx. lines 15-16. See '475 Patent, claim 6, column 29, approx. lines 48-50 and 55-57. See '395 App., claim 20, page 14, approx. compound 14. See '856 App, claim 33, page 28, approx. compound 7 and page 29, column 1, approx. compound 10. Note that the instantly made rejection is an obviousness type double patenting rejection and not a statutory double patenting rejection.

The declaration has been considered, but is not found persuasive. Applicants state that the Kp value is more than 100X lower than that of the prior art compounds, but there was no side by side comparison between all of the compounds of the cited references. In addition, Applicants did not explain how a difference in this value is unexpected. Is it more potent and does it change the dosage requirements? How would one of ordinary skill in the art not deem this unexpected. The utility of the instantly claimed compounds and that of the prior art are the same. The compounds are very similar and to one of ordinary skill in the art the variations would be obvious (see previous office action mailed on 7/15/2008, especially pages 6-10.)

Claims 11 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-41 of U.S. Patent App Num. 2007/0293553 A1 ('553 App). This is a provisional rejection. The instant application is senior and this rejection will be withdrawn should no other rejections remain.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/  
Primary Examiner, Art Unit 1626

Susannah Chung, 2/11/2009